IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

COR 2021 006598

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 63(2)

*Section 67 of the **Coroners Act 2008***

Findings of:	AUDREY JAMIESON, Coroner
Deceased:	Stuart John Noble
Date of birth:	10 September 1974
Date of death:	Between 08 and 09 December 2021
Cause of death:	1(a) Multidrug toxicity (ethanol, quetiapine, baclofen, benzodiazepines)
Place of death:	Carrum Downs Holiday Park, 1165 Frankston - Dandenong Road, Carrum Downs, Victoria, 3201
Keywords:	Suicide; intentional death; baclofen; prescription drugs; Therapeutic Goods Administration

INTRODUCTION

1. On 09 December 2021, Stuart John Noble was 47 years old when he was found deceased at his home following an apparent overdose. At the time of his death, Stuart lived alone in a unit at the Carrum Downs Holiday Park.

2. Stuart is survived by his two children, Gemma and Cody.

Background

3. When Stuart was in his teens, he began a relationship with Megan Knowles. The couple had two children, Gemma and Cody. Megan reported their relationship to be emotionally abusive and 'on again off again' due to Stuart's alcoholism, drug use and inability to hold a job. Stuart was also 'in and out' of gaol during this time.[1]

4. The couple separated in 2010 after approximately 22 years together. Following the couple's separation, Megan and Gemma sustained ongoing emotional abuse from Stuart including threats made towards Megan, and Stuart expressing to Gemma that she was 'dead to him'. Megan and Gemma were both granted Family Violence Intervention Orders preventing contact from Stuart, though he and Gemma reconciled in 2021.

5. Following his separation from Megan, Stuart had at least two other relationships during which he continued to drink heavily, use drugs and display abusive behaviour.[2]

Medical history

6. Stuart had a long history of alcohol and drug abuse with one known episode of drug induced psychosis approximately ten years ago.[3] His alcohol abuse resulted in severe alcoholic pancreatitis and hepatitis.

7. According to his General Practitioner (GP) Dr Andrew Taylor, Stuart struggled with his mood and had an explosive temper. Dr Taylor noted however that Stuart showed no evidence of suicidality.

[1] Coronial Brief (**CB**), Statement of Gemma Knowles.
[2] CB, Statement of Megan Knowles.
[3] CB, Statement of Dr Andrew Taylor.

8. According to Megan, Stuart made one attempt on his life during their relationship by overdosing on quetiapine, which he had been prescribed for the treatment of schizophrenia.[4]

9. In 2021 Stuart was diagnosed with an adrenal adenoma which Dr Taylor commented may have increased his anxiety levels.

10. At the time of his death, Stuart was prescribed the following medications:[5]

    a) Baclofen for treatment of alcohol addiction;

    b) Nitrazepam for treatment of grief reaction;

    c) Quetiapine for treatment of drug induced psychosis;

    d) Tramadol for treatment of right hand pain;

    e) Diazepam; and

    f) Thiamine hydrochloride.

THE CORONIAL INVESTIGATION

11. Stuart's death was reported to the Coroner as it fell within the definition of a reportable death in the *Coroners Act 2008* (the Act). Reportable deaths include deaths that are unexpected, unnatural or violent or result from accident or injury.

12. The role of a coroner is to independently investigate reportable deaths to establish, if possible, identity, medical cause of death, and surrounding circumstances. Surrounding circumstances are limited to events which are sufficiently proximate and causally related to the death. The purpose of a coronial investigation is to establish the facts, not to cast blame or determine criminal or civil liability.

13. Under the Act, coroners also have the important functions of helping to prevent deaths and promoting public health and safety and the administration of justice through the making of comments or recommendations in appropriate cases about any matter connected to the death under investigation.

[4] CB, Statement of Megan Knowles.
[5] CB, Statement of Dr Andrew Taylor.

14. Victoria Police assigned an officer to be the Coroner's Investigator for the investigation of Stuart's death. The Coroner's Investigator conducted inquiries on my behalf, including taking statements from witnesses – such as family, the forensic pathologist, treating clinicians and investigating officers – and submitted a coronial brief of evidence.

15. This finding draws on the totality of the coronial investigation into the death of Stuart John Noble including evidence contained in the coronial brief. Whilst I have reviewed all the material, I will only refer to that which is directly relevant to my findings or necessary for narrative clarity. In the coronial jurisdiction, facts must be established on the balance of probabilities.[6]

MATTERS IN RELATION TO WHICH A FINDING MUST, IF POSSIBLE, BE MADE

Circumstances in which the death occurred

16. On 6 December 2021, Stuart's partner Dianne attended at the Frankston Police Station to report recent harassment and death threats made by Stuart. Police issued a Family Violence Safety Notice preventing Stuart from approaching or contacting Dianne, with a hearing date of 15 December 2021 set for an application for a Family Violence Intervention Order to be heard at Frankston Magistrates Court.

17. At 6:18pm on 6 December 2021, the Family Violence Safety Notice was personally served on Stuart by police officers.[7]

18. On the evening of 7 December 2021, Dianne received calls and voicemail messages from Stuart in which he threatened to slit her throat and have people 'come after her'.

19. At around midday on 8 December 2021, Dianne again attended at Frankston Police Station to report the threats she had received the previous evening. Dianne provided a statement to First Constable Hayley Caling ("FC Caling") before leaving the station around 1pm.

20. FC Caling attempted to call Stuart on two different phone numbers to no avail. She then liaised with Sergeant Michael Spencer ("Sergeant Spencer") who was on duty and requested that he arrest Stuart. Sergeant Spencer attended at the Carrum Downs Holiday Park accompanied by

[6] Subject to the principles enunciated in *Briginshaw v Briginshaw* (1938) 60 CLR 336. The effect of this and similar authorities is that coroners should not make adverse findings against, or comments about, individuals unless the evidence provides a comfortable level of satisfaction as to those matters taking into account the consequences of such findings or comments.

[7] CB, Statement of Detective Leading Senior Constable Leighton Richardson.

three other officers, but they were unable to locate Stuart. They left a message card at his unit requesting he contact FC Caling.

21. On the morning of 9 December 2021, Detective Leading Senior Constable Leighton Richardson ("D/LSC Richardson") was tasked with triaging all family violence incidents reported at Frankston Police Station. Upon reviewing the reports made by Dianne, D/LSC Richardson formed the view that Stuart needed to be arrested and interviewed in relation to the threats he had made towards her.[8]

22. At around 9:15am, D/LSC Richardson arrived at the Carrum Downs Holiday Park accompanied by four other officers. They obtained the key to Stuart's cabin from reception to ensure they could enter the unit without obstruction. D/LSC Richardson knocked and announced himself, to no answer. He unlocked the door and entered the unit, immediately observing Stuart laying on the bed 'clearly deceased'.

23. An Ambulance was requested via police communications. Ambulance Victoria paramedics arrived on scene at approximately 9:35am and pronounced Stuart deceased.

24. A "suicide note" was located within the unit, along with a bottle of baclofen with 11 tablets remaining and three packs of quetiapine with one tablet remaining. The label on the bottle of baclofen identified that it had been prescribed to Stuart by his GP Dr Taylor.

Identity of the deceased

25. On 9 December 2021 Stuart John Noble, born 10 September 1974, was visually identified by his neighbour Adam Pearson, who completed a formal Statement of Identification.

26. Identity is not in dispute and requires no further investigation.

Medical cause of death

27. Forensic Pathologist Dr Hans de Boer from the Victorian Institute of Forensic Medicine (**VIFM**) conducted an external examination on the body of Stuart Noble on 13 December 2021. Dr de Boer reviewed the Victoria Police Report of Death (Form 83), post mortem computed tomography (CT) scan, information from the VIFM contact log and scene photographs and provided a written report of his findings dated 10 March 2022.

[8] CB, Statement of Detective Leading Senior Constable Leighton Richardson.

28. Dr de Boer did not identify the presence of any natural disease, trauma or injury that may have contributed to the death.

29. Toxicological analysis of post-mortem blood samples identified the following:[9]

    g) Ethanol ~ 0.02g/L;

    h) Baclofen ~ 4.8mg/L;

    i) Diazepam ~ 0.1mg/L and its metabolite nordiazepam; and

    j) Nitrazepam ~ 0.01mg/L and its metabolite 7-aminonitrazepam.

30. Quetiapine was also identified in the stomach contents at a level of ~ 134mg.

31. Forensic Toxicologist Ms Grace Wang of the VIFM commented that *'the baclofen and quetiapine detected is consistent with excessive use. In addition, the use of multiple central nervous system depressant drugs such as alcohol and benzodiazepines may result in respiratory depression and sedation, increasing the risk of death.'*[10]

32. Dr de Boer provided an opinion that the medical cause of death was 1 (a) MULTIDRUG TOXICITY (ETHANOL, QUETIAPINE, BACLOFEN, BENZODIAZEPINES).

FURTHER INVESTIGATIONS

33. Having reviewed the coronial brief, medical examiner's report and toxicology report, I became concerned that the death of Stuart Noble occurred in similar circumstances to several other recent Victorian deaths: the baclofen-involved intentional overdose of a person with a history of alcohol misuse and mental ill-health, who was being prescribed the baclofen off-label[11] to treat alcohol use disorder.

Context

34. Baclofen is a derivative of gamma aminobutyric acid (GABA), a major neurotransmitter in the human central nervous system. It is a centrally acting antispastic agent with a spinal site

[9] Court File (**CF**), Toxicology Report of Forensic Toxicologist Grace Wang, dated 25 February 2022.
[10] Ibid.
[11] Prescribing a drug for a purpose or indication not approved by the TGA is commonly referred to as 'off-label' prescribing and is not illegal, although the doctor carries the onus to be satisfied that the prescribing is supported by reasonable quality evidence.

of action, and commonly referred to as a 'muscle relaxant'. It is commonly available in both 10mg and 25mg tablets.

35. The Therapeutic Goods Administration (TGA) has approved baclofen in tablet form for the following specific indications: *suppression of voluntary muscle spasm in: multiple sclerosis; spinal lesions of traumatic, infectious, degenerative, neoplastic and unknown origin, causing skeletal hypertonus and spastic and dyssynergic bladder dysfunction*.[12]

36. There is, however, a growing body of evidence to support the use of baclofen as a treatment for alcohol use disorder. The evidence suggests that it may help those with alcohol use disorder in maintaining abstinence from alcohol, particularly where they have already gone through the process of detoxification.[13] The use of baclofen for this purpose appears to be well established clinical practice.[14]

37. Baclofen is also not specifically contraindicated for the treatment of alcohol use disorder. However, the Product Information contains the following warning under the heading 'SPECIAL WARNINGS AND PRECAUTIONS FOR USE':

    Suicide and suicide-related events have been reported in patients treated with baclofen. In most cases, the patients had additional risk factors associated with an increased risk of suicide including alcohol use disorder […] Close supervision of patients with additional risk factors for suicide should accompany drug therapy.[15]

38. Further, the Product Information states that baclofen should be used with caution in patients with a history of alcoholism, and that increased sedation may occur when taken concomitantly with alcohol.[16]

39. Whilst I accept that there exists a body of evidence suggesting baclofen is effective in the management of alcohol use disorder, I remained concerned about the number of suicides involving baclofen in patients with alcohol use disorder, particularly in light of the TGA's warning to prescribers within the Product Information.

---

[12] Therapeutic Goods Administration, Department of Health and Aged Care, Summary for ARTG Entry: 77576 APO-BACLOFEN baclofen 25mg tablets bottle.
[13] Cochrane Review, *Baclofen for alcohol use disorder*, Agabio R, Saulle R, Rosner S, Minozzi S, dated 13 January 2023.
[14] See my Finding with Inquest into the Death of Robert Love, dated 6 November 2020, and references therein: https://www.coronerscourt.vic.gov.au/sites/default/files/2020-11/RobertThomasLove_083315.pdf
[15] Therapeutic Goods Administration, Department of Health and Aged Care, Australian Product Information Apo-Baclofen (Baclofen) Tablets.
[16] Ibid.

40. Accordingly, I referred the file to the Coroners Prevention Unit (CPU)[17] for review, with a view to identifying any prevention opportunities in line with my prevention role as articulated in the Preamble and Purposes of the *Coroners Act 2008* (Vic).

CPU Review

41. I specifically requested that the CPU contact Dr Taylor to enquire about his prescribing of baclofen to Stuart and patients generally, as well as his views on the use of baclofen to manage alcohol use disorder. I also requested the CPU contact the TGA to learn more about how medicines are approved for specific indications and whether approving baclofen for alcohol use disorder might have a medicines safety benefit.

Dr Andrew Taylor

1. The Pharmaceutical Benefits Scheme (PBS) Patient Summary for Stuart shows that in the 12 months leading up to his death, baclofen was dispensed to him on the following occasions:[18]

    a) 5 March 2021 - 100 tablets on a script from Dr Robert Weiss (one of Dr Taylor's colleagues at Frankston Healthcare)

    b) 14 July 2021 - 100 tablets on a script from Dr Andrew Taylor

    c) 31 August 2021 - 100 tablets on a script from Dr Andrew Taylor

    d) 14 September 2021 - 100 tablets on a script from Dr Andrew Taylor

    e) 18 October 2021 - 100 tablets on a script from Dr Andrew Taylor

2. The CPU wrote to Dr Taylor on 23 March 2023, asking several questions about his rationale for choosing baclofen as a treatment for Stuart's alcohol use disorder and which, if any, safe prescribing measures he put in place.

3. Dr Taylor responded on the same day with a brief letter outlining the following:[19]

[17] The Coroners Prevention Unit (CPU) was established in 2008 to strengthen the prevention role of the coroner. The unit assists the Coroner with research in matters related to public health and safety and in relation to the formulation of prevention recommendations. The CPU also reviews medical care and treatment in cases referred by the coroner. The CPU is comprised of health professionals with training in a range of areas including medicine, nursing, public health and mental health.

[18] PBS Patient Summary for Stuart J Noble for period 9 December 2020 to 9 December 2021, dated 10 March 2023.

[19] Letter from Dr Andrew Taylor to Coroners Court of Victoria, dated 23 March 2023.

a) He commenced prescribing baclofen to patients in 2009. It had been discussed in addiction medicine for some years, but "quality research papers were few" at the time.

b) He had prescribed baclofen to Stuart for at least six years. Stuart was familiar with the medication and had "proven himself safe with it", and as such "no particular safety measures were put in place". He further noted that baclofen is "remarkably safe" provided the dose is escalated slowly.

c) He believes that "all doctors working in the field of drug addiction are now well versed in the use of baclofen".

Therapeutic Goods Administration

4. The CPU wrote to the TGA on 5 April 2023 to seek advice on the process of approving medications for specific indications and the medicines safety implications of prescribing off-label.

5. The Acting Deputy Secretary of the TGA's Health Products Regulation Group, Tracey Duffy, responded by letter dated 10 May 2023. In her letter, Ms Duffy explained the TGA's role in approving medications for specific uses or indications, and their primary need to establish that "the benefits outweigh the risks" for any intended use being assessed. She further explained that this assessment process must be commenced by an external applicant (called the sponsor) rather than by the TGA:

The TGA cannot compel a sponsor to make an application for a new indication for an approved medicine. Furthermore, in the absence of a formal application the TGA does not have the legal authority to grant approval/nor initiate an evaluation of the product for an extension of indication.[20]

6. Ms Duffy noted that to the best of the TGA's knowledge and based on digital files,[21] no sponsor has submitted an application to the TGA to register baclofen for alcohol use disorder.

7. She further noted that while the TGA does not play any medicines safety role in off-label prescribing, other bodies may be responsible for clinical practice regulation in these

[20] Letter from Tracey Duffy to Coroner Audrey Jamieson, dated 10 May 2023.
[21] Ms Duffy advised that the current Australian Register of Therapeutic Goods (ARTG) entry for baclofen commenced in 1991. At that time the TGA used paper files which would need to be recalled and hand searched to categorically confirm if any applications had been made historically.

circumstances; she suggested the Australian Health Practitioners Regulation Agency (AHPRA), the Australian Commission on Safety and Quality in Health Care (ACSQHC) and the Australian medical colleges.

COMMENTS

Pursuant to section 67(3) of the Act, I make the following comments connected with the death.

Victorian Suicide Register

1. The Victorian Suicide Register (VSR) is a database containing detailed information on suicides that have been reported to and investigated by Victorian Coroners between 1 January 2000 and the present.

2. The VSR indicates the annual frequency of suicides occurring in the state of Victoria has been steadily increasing for the past decade, from 550 deaths in 2011 to a peak of 757 deaths in 2022.[22]

3. The primary purpose of gathering suicide data in the VSR is to assist Coroners with prevention-oriented aspects of their suicide death investigations. VSR data is often used to contextualise an individual suicide with respect to other similar suicides; this can generate insights into broader patterns and trends and themes not immediately apparent from the individual death, which in turn can lead to recommendations to reduce the risk that further such suicides will occur in the future

4. So much is still unknown about suicide and, given that every suicide occurs in unique circumstances to a person with a unique history and life experience, possibly there is much we will never be able to quantify and understand. But through recording information about each individual suicide in the VSR, particularly information about the health and other services with whom the person had contact, and then looking at what has happened across time and across people, we hope the VSR can at least lead us to new understandings of how people who are suicidal might better be supported in our community.

[22] Coroners Court Monthly Suicide Data report, March 2023 update. Published 26 April 2023.

Alcohol and suicide

5. I note that there is an increased rate of suicidal behaviour as well as completed suicide among individuals with an alcohol use disorder.[23]

6. Post-mortem studies find that alcohol or other drugs at measurable levels play a role in 30–50% of suicides. Substance misuse predisposes one to suicide by disinhibiting or providing "courage" to overcome resistance to carrying out the act, clouding one's ability to see alternatives and worsening of mood disorders. The association between alcohol consumption and self-harm or suicide is not entirely clear. Theoretically, consumption of alcohol may influence self-harm or suicide due to the depressant influence of the substance itself, or acute alcohol intoxication contributing to disinhibited or impulsive behaviours.

Comments related to Stuart's death

7. The circumstances in which Stuart Noble died - an intentional overdose involving baclofen in a person who previously experienced mental ill-health and was being prescribed baclofen to manage alcohol use disorder - are unfortunately familiar to Victoria's coroners. In my recent finding in the death of Anna Lawrence[24] I noted that among 34 Victorians who died between 2012 and 2021 following a baclofen-involved overdose, most deaths were suicides and (where able to be established) the baclofen had been prescribed to treat the deceased's alcohol dependence.

8. In that finding I reflected upon the practice of baclofen prescribing to treat alcohol use disorder. In particular, I was concerned that despite baclofen not being approved by the TGA in Australia to treat alcohol use disorder, this nonetheless is a very common occurrence. I noted that while there is clinical evidence to support baclofen as a potentially effective treatment for alcohol use disorder, there are also risks in doing so; including that patients with histories of mental ill health, suicidality, polysubstance use, or overdose may self-harm using the drug.

9. Through my investigation into Anna Lawrence's death and broader review of other similar baclofen-involved suicides, I developed a concern that the lack of TGA approval for baclofen to treat alcohol use disorder might be in some ways counterproductive from a medicines safety

[23] American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, fifth edition, 2013, p. 493.
[24] COR 2020 002323; https://www.coronerscourt.vic.gov.au/sites/default/files/COR%202020%20002323%20Form%2038-Finding%20into%20Death%20without%20Inquest.pdf

perspective, given that baclofen is already so widely prescribed off-label for this purpose. I therefore recommended:

i. In the interests of promoting public health and safety and with the aim of preventing similar deaths, I recommend that the Therapeutic Goods Administration consider whether, by revising the Australian Register of Therapeutic Goods entry for Baclofen to include alcohol use disorder as an approved indication, safer Baclofen prescribing practices could be achieved in order to improve the outcome for patients with alcohol use disorder and reduce the risk of death by Baclofen overdose in future.

10. The Acting Deputy Secretary of the TGA's Health Products Regulation Group, Tracey Duffy, responded to this recommendation on 10 May 2023 indicating that the TGA did not have the power to implement independently the recommendation. Tracey Duffey explained, inter alia, that:

Before a medicine, or a new indication for a medicine, can be included on the Australian Register of Therapeutic Goods (ARTG), the TGA must receive an application from an Australian pharmaceutical Sponsor. This Sponsor must be willing to accept the responsibilities of selling prescription medicines in Australia. […] For products containing baclofen to be registered for alcohol use disorder, an incorporated body or resident of Australia would need to be willing to accept responsibility as the Australian Sponsor for this extended indication and submit the relevant supporting data to the TGA. The TGA cannot compel a sponsor to make an application for a new indication for an approved medicine.

11. Accepting this explanation, I have considered what else could be done to support doctors in safe prescribing of baclofen and particularly in their management of patients who might be particularly at risk of overdose. Given that the baclofen prescribers in the deaths of both Stuart Noble and Anna Lawrence (and a good number of the other baclofen-involved deaths that have recently occurred in Victoria) were general practitioners, I concluded these issues may potentially be of interest to the Royal Australian College of General Practitioners (RACGP).

12. I note that the RACGP have either directly produced or have otherwise facilitated doctors' access to a number of excellent resources about alcohol and other drug treatment, including the Commonwealth Government-commissioned Guidelines for the Treatment of Alcohol

Problems.[25] These Guidelines address baclofen prescribing, and several RACGP members were involved in their development.

13. Therefore, I do not make any recommendation in this matter. Instead, I ask the RACGP's Addiction Medicine Specific Interests Group to consider whether the current resources available to general practitioners offer sufficient guidance on how to prescribe baclofen safely to treat alcohol use disorder and manage vulnerable patient groups who may be at risk of overdose.

FINDINGS AND CONCLUSION

1. Pursuant to section 67(1) of the *Coroners Act 2008* I make the following findings:

   a) the identity of the deceased was Stuart John Noble, born 10 September 1974;

   b) the death occurred between 08 and 09 December 2021 at 1165 Frankston - Dandenong Road, Carrum Downs, Victoria, 3201;

   c) I accept and adopt the medical cause of death as ascribed by Dr Hans de Boer and find that Stuart John Noble died from multidrug toxicity (ethanol, quetiapine, baclofen, benzodiazepines) in circumstances where I also find he intended to take his own life.

2. AND, whilst the exact precipitating factors leading Stuart John Noble to take his own life will never be known, the evidence before me suggests that his recent relationship breakdown and episodes of family violence on a background of long-term alcoholism and drug use may have influenced him to adopt the course of action he ultimately chose.

3. AND FURTHER, although Stuart John Noble was not identified by his doctor to be suicidal, his alcohol use disorder, propensity for anger and reliance on quetiapine, an anti-psychotic medication, suggests he suffered from mental ill-health. I find that the circumstances of the death of Stuart John Noble highlight the risks associated with prescribing baclofen for alcohol use disorder, particularly in individuals with mental ill-health.

Pursuant to section 73(1B) of the Act, I order that this finding be published on the Coroners Court of Victoria website in accordance with the rules.

[25] Specialty of Addiction Medicine, Faculty of Medicine and Health, The University of Sydney, *Guidelines for the Treatment of Alcohol Problems (4th edition)*, 2021. https://ses.library.usyd.edu.au/handle/2123/28146

I convey my sincere condolences to Stuart's family for their loss.

I direct that a copy of this finding be provided to the following:

Gemma Knowles

Cody Knowles-Noble

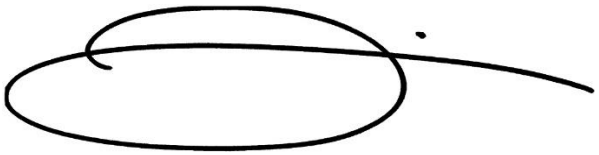
Detective Leading Senior Constable Leighton Richardson, Coroner's Investigator

Dr Andrew Taylor

Therapeutic Goods Administration

Royal Australian College of General Practitioners

Signature:



AUDREY JAMIESON

CORONER

Date: 29 May 2023

NOTE: Under section 83 of the ***Coroners Act 2008*** ('the Act'), a person with sufficient interest in an investigation may appeal to the Trial Division of the Supreme Court against the findings of a coroner in respect of a death after an investigation. An appeal must be made within 6 months after the day on which the determination is made, unless the Supreme Court grants leave to appeal out of time under section 86 of the Act.